UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DONNA EMLEY, DENNIS EMLEY, Plaintiffs, v. WAL-MART STORES, INC., L.N.K. INTERNATIONAL, INC., L. PERRIGO COMPANY, Defendants.	)	No. 1:17-cv-02350-SEB-TAB

ORDER DENYING DEFENDANT'S MOTION FOR RECONSIDERATION

This litigation has arisen from Plaintiff Donna Emley's claims of injury resulting from her ingestion of Equate acetaminophen, manufactured by Defendants L. Perrigo Company ("Perrigo") and L.N.K. International ("L.N.K.") and sold by Defendant Wal-Mart Stores, Inc. ("Wal-Mart"), for which no warnings of her potential injuries were included on the labels for these drugs. On January 8, 2020, we denied Defendants' Petition for Certification of Interlocutory Appeal [Dkt. 202] of our Entry on Motions for Summary Judgment, [Dkt. 199], which ruling turned on the issue of whether Plaintiffs' state law failure-to-warn claims are preempted by federal law. [Dkt. 323]. Now before us is Defendant Perrigo's Motion for Reconsideration of Order Denying Petition for Certification of Interlocutory Appeal. [Dkt. 325].

Background

As explicated in detail in our previous orders, over-the-counter acetaminophen is manufactured and sold pursuant to the FDA's Over-The-Counter Drug Monograph Review Process. [Dkt. 199, at 7; Dkt. 323, at 7]. A final monograph "constitutes final agency action from which appeal lies to the courts." 21 C.F.R. § 330.10(a)(11). To date, however, no final monograph for acetaminophen has been enacted or adopted by the FDA. Thus, regulation of over-the-counter acetaminophen is largely governed by a tentative final monograph.[1]

On June 27, 2019, we granted in part and denied in part Defendants' motions for summary judgment ("Summary Judgment Order"), addressing the question of whether manufacturers of over-the-counter acetaminophen are subject to the requirement to provide the precise warnings established in an agency monograph that has yet to be fully adopted. After conducting a detailed review of the applicable regulatory scheme, we concluded that they were not so bound, for the following reasons:

> [T]he relevant regulations do not authorize any enforcement actions based on non-compliance until after a monograph is finalized, *see* 21 C.F.R. § 330.10(a)(9); 21 C.F.R. § 330.10(b); Defendants have failed to identify any manufacturer or distributor operating under a tentative final monograph that had ever faced regulatory consequences for deviating from the "exact language" of a tentative final monograph; a tentative final monograph, by its very terms, has the legal status of a proposed rule and thus does not, as we have said, wield the force and effect of federal law; acetaminophen was not subject to 21 C.F.R. § 330.13(b)(2), which authorizes regulatory action against manufacturers of certain drugs that are not labeled in compliance with their corresponding tentative final monographs; and, finally, draft guidance issued by the FDA in 2011 indicated that obligations to

[1] Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph," 53 Fed. Reg. 46204 (Nov. 16, 1988).

> comply with marketing requirements set out in a monograph do not attach until a final monograph becomes effective.

[Dkt. 323, at 10]. On July 26, 2019, Defendants collectively petitioned the Court to certify our Summary Judgment Order for interlocutory appeal with respect to the preemption question. [Dkt. 202, Dkt. 204]. Granting such requests is predicated on certain criteria having been established: "there must be a question of *law*, it must be *controlling*, it must be *contestable*, and its resolution must promise to *speed up* the litigation." *Ahrenholtz v. Bd. of Trs. of Univ. of Ill.*, 219 F.3d 674, 675 (7th Cir. 2000) (*emphasis in original*).

As noted in our denial of the Petition for Certification of Interlocutory Appeal ("Certification denial)," the meaning of "contestability" constitutes the "dominant dispute" between the parties. Defendants have argued that the "preemption question . . . is contestable because it is one of first impression in this Circuit and nationally." In response, Plaintiffs advocate for a more stringent standard, arguing that "the mere lack of judicial precedent" is an inadequate for interlocutory appeal where there are no "conflicting opinions regarding the issue of law." In their reply brief, Defendants insist that "novel and difficult questions of first impression are contestable."

On January 8, 2020, again after careful consideration of these views and arguments, we denied Defendants' Petition for Certification of Interlocutory Appeal, based on our conclusion that "the prevailing approach adopted by district courts, including ours, is to impose a rigid standard for 'contestability' which can be satisfied

only in rare circumstances, such as when there is a 'substantial likelihood' that the district court's order would be reversed on appeal." [Dkt. 323, at 11]. As we further explained:

> The mere lack of judicial precedent on the issues does not establish substantial ground for difference of opinion. Indeed, if interlocutory appeals were permissible whenever there is merely the lack of judicial precedent, the effect would be no more than to obtain an appellate stamp of approval on the ruling(s) by the trial court. Instead, we examine the strength of the arguments in opposition to the challenged ruling. This analysis includes examining whether other courts have adopted conflicting positions regarding the issue of law proposed for certification.

[*Id.*] (*internal citations omitted*). Applying this rule to the case before us, we concluded:

> Defendants stress the "novelty" of the issues presented here but fail to establish how novelty alone warrants a departure from the preferred course of litigation culminating in an appeal. While the relevant regulations do leave ample room for reasonable disagreement as to the meaning of the term "applicable monograph," this disagreement, unsupported by conflicting authorities, does not indicate a substantial likelihood that our Summary Judgment Order would be reversed on appeal. Accordingly, we hold that the issue of whether Plaintiffs' failure-to-warn claims are preempted by federal law is not "contestable."

[*Id.* at 17]. On January 13, 2020, Defendant Perrigo moved for reconsideration of our Certification denial.[2]

Discussion

A motion for reconsideration "serves the limited function of correcting manifest errors of law or fact or presenting newly discovered evidence." *Thomas v. Johnston*, 215 F.3d 1330 (7th Cir. 2000). The Seventh Circuit has defined the proper role of motions for reconsideration as follows:

> A motion for reconsideration performs a valuable function where the Court has patently misunderstood a party, or has made a decision outside the adversarial

[2] Although each defendant individually moved for summary judgment on preemption grounds, and all defendants joined together on the Petition for Certification of Interlocutory Appeal, only Defendant Perrigo has moved for reconsideration of our Certification denial.

> issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension. A further basis for a motion to reconsider would be a controlling or significant change in the law or facts since the submission of the issue to the Court.

Bank of Waunakee v. Rochester Cheese Sales, Inc., 906 F.2d 1185, 1191 (7th Cir. 1990) (*quoted in Elder Care Providers of Indiana, Inc. v. Home Instead, Inc*., No. 1:14-CV-01894-SEB-MJD, 2017 WL 4287540, at *1 (S.D. Ind. Sept. 26, 2017)). It is within the sound discretion of the district court whether to grant a motion for reconsideration. *Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 955 (7th Cir. 2013).

Perrigo does not contend that we have patently misunderstood the parties, made a decision outside of the issues presented, or failed to apprehend legal authorities;[3] rather, Perrigo maintains that there has been "significant change to the relevant legal landscape" following the submission of the Petition for Certification of Interlocutory Appeal, citing the holding in *Bailey v. Rite Aid Corporation*, which it describes as a newly-discovered "conflicting authority" issued after Defendants filed their petition. No. 18-CV-06926-YGR, 2019 WL 4260394 (N.D. Cal. Sept. 9, 2019).

[3] Perrigo critiques the statement in our Certification Order that: "If the tentative final monograph did have the force and effect of a final regulation, then Defendants would not have been permitted to deviate from its 'exact language' by virtue of the non-binding guidance from the FDA—which would not supersede codified federal regulations such as the 'exact language' provision." Perrigo asserts that there is "conflicting authority" as to this point, noting that other courts have recognized the FDA's authority to decline to enforce its own regulations. However, Perrigo does not assert that its Motion for Reconsideration should be granted on the grounds that we committed a manifest error of law on this issue, or otherwise explain how this contestation provides a basis for granting its Motion for Reconsideration. It appears that Perrigo has raised this objection to avoid any waiver of its argument that the FDA's guidance supports its preemption theory. Moreover, as Perrigo acknowledges, our Summary Judgment Order did not turn on this point. Nor did our Certification Order. For these reasons, we conclude that Perrigo has articulated no reason to justify reconsideration of our Certification Order.

While Perrigo is correct in that the *Bailey* decision was published following the submission of Defendants' Petition for Interlocutory Appeal, Perrigo has sidestepped the fact that *Bailey* was actually handed down eleven days *before* Defendants' reply brief in support of their petition was filed, which omitted any mention or discussion of *Bailey*. Perrigo provides no explanation for its omission.

That the Court could hold that the presence of conflicting authorities was necessary to establish "contestability" could not have escaped Perrigo's thinking, given that this was the standard advocated by Plaintiffs in their opposition brief. Perrigo could have cited *Bailey* as a conflicting authority, but it did not. Instead, it continued to stress that the legal issue was one of "first impression" and that the only case cited by the parties as addressing the relevant preemption, was, in fact, distinguishable. A motion for reconsideration is not available to introduce new evidence or arguments that could have been raised in the initial briefing. *See Direct Enterprises, Inc. v. Sensient Colors LLC*, No. 1:15-CV-01333-JMS-TAB, 2018 WL 1070288, at *2 (S.D. Ind. Feb. 23, 2018) *Elder Care Providers*, 2017 WL 4287540, at *3; *Walker v. Trailer Transit, Inc*., No. 1:13-CV-00124-TWP, 2015 WL 735766, at *2 (S.D. Ind. Feb. 19, 2015), *aff'd*, 824 F.3d 688 (7th Cir. 2016). Perrigo's motion for reconsideration is unavailing when its purpose and effect is to give it a second bite of the apple following an adverse ruling.[4] Accordingly, we **deny** Perrigo's Motion for Reconsideration.

[4] Perrigo's Motion for Reconsideration notes that it conducted additional research "in response to the Court's ruling denying interlocutory appeal . . . to determine if there was any potential remedy in response to the Court's ruling." Perrigo advances no reason to explain its failure to complete this research prior to the close of briefing. Thus it appears that it waited until it

That said, we would not reverse our Certification denial in light of *Bailey*, even if the Motion for Reconsideration were granted.

In *Bailey*, the plaintiff objected to defendant's marketing of its over-the-counter, rapid release acetaminophen product, arguing that the product should not have been marketed as a "rapid release" product when it did not actually work faster than non-rapid release products. The court agreed with defendant that acetaminophen's tentative final monograph has the "force and effect of a final monograph," although it concluded that the provisions of the monograph did not preempt plaintiff's claims. 2019 WL 4260394, at *4. Perrigo argues that the *Bailey* holding, with respect to the effect of the tentative final monograph, conflicts with our own interpretation, the effect of which makes the preemption question "contestable." We do not construe the holding of *Bailey* in that fashion.

As Perrigo notes, the *Bailey* court's holding relied on a 2006 FDA warning letter[5] to an acetaminophen manufacturer that threatened enforcement action because of the manufacturer's failure to include required warnings on its product's labels. According to the *Bailey* Court, "the FDA relied on the 1988 [tentative final monograph] for authority to take such action." Perrigo maintains that the letter establishes that FDA enforcement

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received our unfavorable decision to do so. Although *Bailey* was published eleven days before Perrigo filed its Reply brief, it took Perrigo only five days following the entry of our Certification denial to locate *Bailey* and brief it for the purposes of its Motion for Reconsideration. Reasonable diligence could have uncovered *Bailey* in time to present it to the Court while Defendants' petition was pending. *See Gen. Ass'n of Regular Baptist Churches v. Scott*, 549 F. App'x 531, 534 (7th Cir. 2013).

[5] FDA Warning Letter to Direct Dispensing, FLA-07-02 (Nov. 2, 2006).This warning letter was also never discussed in Perrigo's earlier briefs. In its Motion for Reconsideration, Perrigo states its "research did not disclose" the letter.

action has been taken in the past against manufacturers who do not comply with a tentative final monograph. Perrigo also asserts that the letter reflects the FDA's interpretation, which is entitled to substantial deference, that the tentative final monograph binds manufacturers.

Perrigo's Motion for Reconsideration omits any discussion of what is actually stated in the FDA's 2006 warning letter, which acknowledges that "acetaminophen . . . is not yet subject to a final OTC drug monograph," and states that the products are misbranded under 21 U.S.C. § 352(f)(2) for failing to include "all warnings presently required for OTC acetaminophen-containing drug products." There were no warnings on the product's labels regarding the use of the product with alcoholic beverages (21 C.F.R. § 201.322), or during pregnancy (21 C.F.R. § 201.63), or with children under age three (21 C.F.R. § 369.21). These warnings are mandated by codified regulations, established outside of the monograph scheme, applicable to over-the-counter acetaminophen; they are *not* set forth in the tentative final monograph. Thus, contrary to the *Bailey* court's holding, the FDA did not rely on the tentative final monograph to initiate enforcement action against a manufacturer, relying instead on codified warnings that were separate and distinct from the tentative final monograph. Additionally, the FDA letter plainly distinguished between tentative final monographs and final monographs, demanding compliance with only the latter.[6]

[6] Perrigo has elected not to address the *Bailey* court's reliance on 21 C.F.R. § 330.14(h) for its holding. This section provides that when an over-the-counter tentative final monograph "has not been finalized and finalization is not imminent . . . the agency may publish a notice of enforcement policy that allows marketing to begin pending the completion of the final

Accordingly, even if we were persuaded that our denial of certification justifies reconsideration, we would not likely do so based on a single federal district court outside our Circuit, in which the reasoning is easily distinguishable. There simply has been no showing of a substantial likelihood that our Summary Judgment Order would be reversed on appeal.

CONCLUSION

For the reasons set forth herein, Defendant Perrigo's Motion for Reconsideration [Dkt. 325] is **DENIED.**

IT IS SO ORDERED.

Date: 01/31/2020

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

monograph[.]" Perrigo has never invoked § 330.14(h) in support of its preemption argument, nor has Perrigo asserted that the FDA has published such a notice of enforcement policy. We therefore follow Perrigo's lead in disregarding the *Bailey* court's reliance on § 330.14(h), which appears misplaced.

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